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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,433	09/19/2008	Kevin D. Cooper	CASEP0931WOUS	8758

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John T. WIEDEMANN  
Calfee ,Halter & Griswold LLP  
1400 McDonald Investment Center  
800 Superior Avenue  
Cleveland, OH 44114-2688

EXAMINER
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WARD, PAUL V

ART UNIT	PAPER NUMBER
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1624

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06/21/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/599,433	<b>Applicant(s)</b> COOPER ET AL.	
	<b>Examiner</b> PAUL V. WARD	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3-9-07</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of species without traverse of in the reply filed on June 6, 2011 is acknowledged.

### ***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific compounds, does not reasonably provide enablement for phthalocyanine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with claim 2.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific compounds disclosed in the specification, does not reasonably provide enablement for **phthalocyanine** compounds broadly. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.

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- 3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Level of ordinary skill in the art.

See below:

1) Nature of the invention.

The nature of the invention is a pharmaceutical composition containing a phthalocyanine. The nature of the invention using the type phthalocyanine is not set forth nor the location of attachment.

2) State of the prior art.

The state of the prior art is that complex phthalocyanine are known as compositions for PDT. There is no universal core structure for phthalocyanine molecules with physical and chemical properties which are indicative of the class of compounds.

3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The quantity of experimentation needed is undue.

4) Level of predictability in the art.

The art pertaining for the compositions are high as phthalocyanine are compound specific and not all phthalocyanine have the ability to produce a composition for PDT.

5) Amount of direction and guidance provided by the inventor.

There is no guidance provided as all the examples in the specification are drawn to the preparation of specific compounds disclosed and not to all phthalocyanine.

6) Existence of working examples.

As discussed above, working examples are drawn to the preparation of specific compounds disclosed in the specification and not to all phthalocyanine.

7) Breadth of claims.

The breadth of the recited phthalocyanine renders the claim overly broad.

8) Level of ordinary skill in the art.

The level of ordinary skill in the art is high due to the unpredictability in the chemical art.

Therefore, as discussed above, to practice the claimed invention herein, a person of ordinary skill in the art would have to engage in undue experimentation to test which phthalocyanine can be used in the instant claim, with no assurance of success.

2. Claims 1-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The issues concerning the meaning of “phthalocyanine” fail to comply with the written description requirement. Claim 1 does not contain a generic formula indicating structural makeup for Applicant’s invention.

According to the MPEP § 2163, “a question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently (see, e.g., LizardTech, Inc. v. Earth Resource Mapping, Inc., 424 F.3d 1336, 1345, 76USPQ2d 1724, 1733 (Fed. Cir. 2005); Enzo Biochem, 323 F.3d at 968, 63 USPQ2d at 1616 (Fed. Cir. 2002); Eli Lilly, 119 F.3d 1559, 43 USPQ2d 1398), a

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new or amended claim wherein a claim limitation has been added or removed, or a claim to entitlement of an earlier priority date or effective filing date under 35 U.S.C. 119, 120, or 365(c). Most typically, the issue will arise in the context of determining whether new or amended claims are supported by the description of the invention in the application as filed (see, e.g., *In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989)), whether a claimed invention is entitled to the benefit of an earlier priority date or effective filing date under 35 U.S.C. 119, 120, or 365(c) (see, e.g., *New Railhead Mfg. L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 63 USPQ2d 1843 (Fed. Cir. 2002); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998); *Fiers v. Revel*, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993); *In re Ziegler*, 992 F.2d 1197, 1200, 26 USPQ2d 1600, 1603 (Fed. Cir. 1993)), or whether a specification provides support for a claim corresponding to a count in an interference (see, e.g., *Fields v. Conover*, 443 F.2d 1386, 170 USPQ 276 (CCPA 1971)). Compliance with the written description requirement is a question of fact, which must be resolved on a case-by-case basis. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991).

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) (“we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims”).

However, as discussed in paragraph I., *supra*, the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention

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has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. For example, consider the claim "A gene comprising SEQ ID NO:1." A determination of what the claim as a whole covers may result in a conclusion that specific structures such as a promoter, a coding region, or other elements are included. Although all genes encompassed by this claim share the characteristic of comprising SEQ ID NO:1, there may be insufficient description of those specific structures (e.g., promoters, enhancers, coding regions, and other regulatory elements) which are also included. The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. For example, even though a genetic code table would correlate a known amino acid sequence with a genus of coding nucleic acids, the same table cannot predict the native, naturally occurring nucleic acid sequence of a naturally occurring mRNA or its corresponding cDNA. Cf. *In re Bell*, 991 F.2d 781, 26 USPQ2d 1529 (Fed.

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Cir. 1993), and *In re Deuel*, 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995) (holding that a process could not render the product of that process obvious under 35 U.S.C. 103). The Federal Circuit has pointed out that under United States law, a description that does not render a claimed invention obvious cannot sufficiently describe the invention for the purposes of the written description requirement of 35 U.S.C. 112. *Eli Lilly*, 119 F.3d at 1567, 43 USPQ2d at 1405. Compare *Fonar Corp. v. General Electric Co.*, 107 F.3d 1543, 1549, 41 USPQ2d 1801, 1805 (Fed. Cir. 1997) (“As a general rule, where software constitutes part of a best mode of carrying out an invention, description of such a best mode is satisfied by a disclosure of the functions of the software. This is because, normally, writing code for such software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed. \* \* \* Thus, flow charts or source code listings are not a requirement for adequately disclosing the functions of software.”).

A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a “laundry list” disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not “reasonably lead” those skilled in the art to any particular species); *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967) (“If n-propylamine had been used in making the compound instead of n-butylamine, the compound of claim 13 would have resulted. Appellants submit to us, as they did to the



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board, an imaginary specific example patterned on specific example 6 by which the above butyl compound is made so that we can see what a simple change would have resulted in a specific supporting disclosure being present in the present specification. The trouble is that there is no such disclosure, easy though it is to imagine it.”) (emphasis in original); *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000) (“the specification does not clearly disclose to the skilled artisan that the inventors ... considered the ratio... to be part of their invention .... There is therefore no force to Purdue’s argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the [later-filed] claims carved out a patentable portion”).”

Applicants are reminded of what the U.S. Court of Appeals Federal Circuit wrote in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398, “[I]n claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus.” “A definition by function, as we have previously indicated, doesn’t not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing *Amgen*).” It is only a definition of a useful result rather than a definition of what achieves that result.” “The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d

1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does “little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.””).

3. Claims 2-33 are rejected because they are dependent upon a rejected base claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Kenney et al. (WO92/01753).

Kenney discloses phthalocyanine compounds and compositions use for treating epithelia cancer. (See pages 1-20 and Table I). These compounds, compositions and methods read on the instant claim. . Since Kenney teaches the exact compounds, compositions and method, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

5. Claims 1-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Kenney et al. (WO95/06688).

Kenney discloses phthalocyanine compounds and compositions use for treating epithelia cancer. (See pages 10-19 and Examples). These compounds, compositions and methods read on the instant claim. . Since Kenney teaches the exact compounds,

compositions and method, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

6. Claims 1-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Cook et al. (WO 02/096913).

Cook discloses phthalocyanine compounds and compositions use for treating epithelia cancer. (See pages 1-23 and Examples). These compounds, compositions and methods read on the instant claim. . Since Cook teaches the exact compounds, compositions and method, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

7. Claims 1-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al. (EP/0633024).

Taylor discloses phthalocyanine compounds and compositions use for treating epithelia cancer. (See pages 1-7). These compounds, compositions and methods read on the instant claim. Since Taylor teaches the exact compounds, compositions and method, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

8. Claims 1-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Love (EP/0720853).

Love discloses phthalocyanine compounds and compositions use for treating epithelia cancer. (See pages 1-5). These compounds, compositions and methods read on the instant claim. Since Love teaches the exact compounds, compositions and method, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

***Claim Rejections - 35 USC § 103***

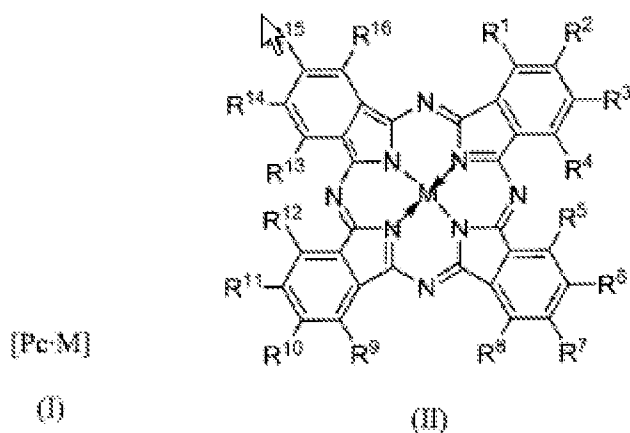
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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenney et al. (WO92/01753).

Applicants claim phthalocyanine compounds and compositions of formula I & II:



wherein all the variables are defined in the claim. Additionally, Applicant claims a method for treating epithelial cancer using said composition.

Kenney discloses a generic group of phthalocyanine compositions and a method of treating epithelial cancer, which embraces Applicants' claimed compounds and methods. (See pages 1-20 and formula I and Examples). The claims differ from the reference by reciting specific species and a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including

those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties, and thus, the same use as taught for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. A prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. Thus, Applicant's claims are obvious, and therefore, rejected under 35 U.S.C. 103.

10. Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenney et al. (WO95/06688).

Kenney discloses a generic group of phthalocyanine compositions and a method of treating epithelial cancer, which embraces Applicants' claimed compounds and methods. (See pages 10-20 and formula I and Examples). The claims differ from the reference by reciting specific species and a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties, and thus, the same use as taught for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. A prior art disclosed genus of useful compounds is sufficient to render prima

facie obvious a species falling within a genus. Thus, Applicant's claims are obvious, and therefore, rejected under 35 U.S.C. 103.

11. Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over. Cook et al. (WO2/096913).

Cook discloses a generic group of phthalocyanine compositions and a method of treating epithelial cancer, which embraces Applicants' claimed compounds and methods. (See pages 1-23 and formula I and Examples). The claims differ from the reference by reciting specific species and a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties, and thus, the same use as taught for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. A prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. Thus, Applicant's claims are obvious, and therefore, rejected under 35 U.S.C. 103.

12. Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over. Taylor et al. (EP/0633024).

Taylor discloses a generic group of phthalocyanine compositions and a method of treating epithelial cancer, which embraces Applicants' claimed compounds and

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methods. (See pages 1-7). The claims differ from the reference by reciting specific species and a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties, and thus, the same use as taught for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. A prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. Thus, Applicant's claims are obvious, and therefore, rejected under 35 U.S.C. 103.

13. Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over. Love (EP/0720853).

Love discloses a generic group of phthalocyanine compositions and a method of treating epithelial cancer, which embraces Applicants' claimed compounds and methods. (See pages 1-5). The claims differ from the reference by reciting specific species and a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties, and thus, the same use as taught

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for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. A prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. Thus, Applicant's claims are obvious, and therefore, rejected under 35 U.S.C. 103.

### ***Conclusion***

Claims 1-33 are pending. Claims 1-33 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL V WARD whose telephone number is 571-272-2909. The examiner can normally be reached on M-F 8 am to 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**/PAUL V WARD/  
Primary Examiner, Art Unit 1624**